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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,794	09/17/2003	Ming-Hui Wei	CL001164CIP-DIV II	3773

25748 7590 05/19/2006

CELERA GENOMICS
ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY
45 WEST GUDE DRIVE
C2-4#20
ROCKVILLE, MD 20850

EXAMINER	
HUMPHREY, DAVID HAROLD	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,794	WEI ET AL.	
	Examiner	Art Unit	
	David Humphrey	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,12 and 24-39* is/are pending in the application.

4a) Of the above claim(s) *12 and 24-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 27-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/08/04;12/12/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Attached SEQUENCE Comparison

DETAILED ACTION

1. Applicants' election of Group I, claims 3 and 27-39, without traverse in the reply filed on April 13, 2006 is acknowledged.

2. Claims 3, 12, and 24-39, are pending.

Claims 12, and 24-26, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.

Claims 3, and 27-39, are examined on the merits.

Specification

3. Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 12, lines 23 and 27, for example.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 3, and 27-39 are rejected under 35 U.S.C. §102(e) as being anticipated by Yue et al. (WO 01/96547 A2; International Filing Date 14 June 2001; effective filing date 30 June 2000).

The claims are drawn to an isolated antibody that selectively binds to a polypeptide wherein the amino acid sequence consists of SEQ ID NO: 2. Claim 27 recites an antibody that selectively binds to a polypeptide wherein the amino acid sequence comprises SEQ ID NO: 2. The claims further recite the limitations wherein the antibody is monoclonal, coupled to a detectable substance, part of a composition that includes a pharmaceutically acceptable carrier. The claims additionally recite isolated antibody fragments such as Fab, $F(ab')_2$, and Fv that selectively bind to a polypeptide of SEQ ID NO: 2.

Yue et al. teach an isolated antibody that selectively binds to a polypeptide called PKIN (a human kinase protein; SEQ ID NO: 7), which is 100% sequence identical to

claimed SEQ ID NO: 2, over amino acids 1-252 and 98% overall (amino acids 1-257) see the attached sequence alignment and page 12, lines 12-18. Yue et al. teach both polyclonal and monoclonal antibodies that bind the PKIN protein, see page 48, lines 5-9. Yue et al. teach administering the antibody with a detectable label, see page 58, lines 12-15. Yue et al. teach antibodies that bind PKIN used in compositions with a pharmaceutically acceptable carrier, see page 56, lines 15-20, and page 128, claims 30-42. Additionally, Yue et al. teach fragments of antibodies such as Fab, and $F(ab')_2$ and Fv which are capable of binding epitopic determinants, see page 18, lines 12-18.

It is noted that claims 3, 28, 30, 32, 34, 36, and 38, are drawn to an antibody or antibody fragments that bind to a polypeptide wherein the amino acid sequence *consists* of SEQ ID NO: 2. SEQ ID NO:2 contains 257 amino acids. The antibody or antibody fragments of Yue et al. bind to a polypeptide that contains 497 amino acids of which the first 252 amino acids are identical to claimed SEQ ID NO: 2. The claimed sequence contains only five amino acids at the C-terminus that are not included in the sequence of Yue et al. Therefore, it is the Examiner's contention that any polyclonal or monoclonal antibodies raised using SEQ ID NO: 2 would cross-react with PKIN of Yue et al.

Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibody with the antibody of Yue et al., the burden of proof is upon the Applicants to show a distinction between the structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922

1923 (PTO Bd. Pat. App. & Int.).

Thus, the instant invention is anticipated by Yue et al.

6. Claims 3, and 27-39, are rejected under 35 U.S.C. §102(e) as being anticipated by Yu et al. (United States Patent Application Publication 2002/0123622; effective filing date 12/27/2000).

The claims are drawn to an isolated antibody that selectively binds to a polypeptide wherein the amino acid sequence consists of SEQ ID NO: 2. Claim 27 recites an antibody that selectively binds to a polypeptide wherein the amino acid sequence comprises SEQ ID NO: 2. The claims further recite the limitations wherein the antibody is monoclonal, coupled to a detectable substance, part of a composition that includes a pharmaceutically acceptable carrier. The claims additionally recite isolated antibody fragments such as Fab, $F(ab')_2$, and Fv that selectively bind to a polypeptide of SEQ ID NO: 2.

Yu et al. teach an isolated antibody that selectively binds to a polypeptide called NHP (**n**ovel **h**uman **p**rotein with structural similarity to serine-threonine kinases, particularly Citron rho-interacting kinases, see page 1, paragraph 4, lines 1-8; page 8, paragraph 73, lines 1-4; SEQ ID NO: 4), which is 100% sequence identical to claimed SEQ ID NO: 2, over amino acids 1-252 and 98% overall (amino acids 1-257) see the attached sequence alignment and page 20, lines 12-18. Yu et al. teach both polyclonal and monoclonal antibodies that bind NHP, see page 8, paragraph 73, lines 5-9. Additionally, Yu et al. teach fragments of antibodies such as Fab, and $F(ab')_2$ and

single chain antibodies (Fv) which are capable of binding epitopic determinants, see page 8, paragraph 73, lines 5-9, and page 9, paragraph 79, lines 1-7. Yu et al. teach that the antibodies may be administered as part of patient treatment methods, see page 5, paragraph 43, lines 2-14 and page 8, paragraph 74, lines 12-15. Yu et al. further teach antibodies with a detectable label, see page 4, paragraph 37, lines 8-11.

It is noted that claims 3, 28, 30, 32, 34, 36, and 38, are drawn to an antibody or antibody fragments that bind to a polypeptide wherein the amino acid sequence *consists* of SEQ ID NO: 2. SEQ ID NO:2 contains 257 amino acids. The antibody or antibody fragments of Yu et al. bind to a polypeptide that contains 1958 amino acids of which the first 252 amino acids are identical to claimed SEQ ID NO: 2. The claimed sequence contains only five amino acids at the C-terminus that are not included in the sequence of Yu et al. Therefore, it is the Examiner's contention that any polyclonal or monoclonal antibodies raised using SEQ ID NO: 2 would cross-react with NHP of Yu et al.

Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibody with the antibody of Yu et al., the burden of proof is upon the Applicants to show a distinction between the structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Thus, the instant invention is anticipated by Yu et al.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Humphrey whose telephone number is (571) 272-5544. The examiner can normally be reached on Mon-Fri 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Humphrey, Ph.D.

May 15, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER

```
RESULT 4
AAE16261
ID   AAE16261 standard; protein; 497 AA.
XX
AC   AAE16261;
XX
DT   26-MAR-2002  (first entry)
XX
DE   Human kinase PKIN-7 protein.
XX
KW   Human; kinase; PKIN-7; cancer; leukaemia; adenocarcinoma; osteoarthritis;
KW   immune disorder; atherosclerosis; Crohn's disease; Hodgkin's disease;
KW   Acquired Immune Deficiency Syndrome; AIDS; Addison's disease; anaemia;
KW   allergy; asthma; adult respiratory distress syndrome; multiple sclerosis;
KW   autoimmune thyroiditis; bronchitis; diabetes mellitus; osteoporosis;
KW   Good pasture's syndrome; Graves' disease; pancreatitis; psoriasis;
KW   rheumatoid arthritis; ulcerative colitis; cirrhosis; Cushing's syndrome;
KW   hepatitis; hypothyroidism; cerebral palsy; cataract; angina pectoris;
KW   cardiovascular disease; hypertension; vasculitis; myocarditis; obesity;
KW   congestive heart failure; ischaemic heart disease; lung tumour; gout;
KW   fatty liver; Niemann-Pick's disease; gene therapy.
XX
OS   Homo sapiens.
XX
FH   Key             Location/Qualifiers
FT   Domain          86. .124
FT                   /label= Protein_kinase_domain
FT   Domain          96. .153
FT                   /label= Protein_kinase_domain
FT   Domain          97. .360
FT                   /note= "Eukaryotic protein kinase domain"
FT   Domain          98. .241
FT                   /label= Protein_kinase_domain
FT   Domain          99. .349
FT                   /label= Protein_kinase_domain
FT   Domain          101. .241
FT                   /label= Protein_kinase_domain
FT   Domain          102. .241
FT                   /label= Protein_kinase_domain
FT   Domain          249. .349
FT                   /label= Protein_kinase_domain
FT   Domain          258. .445
FT                   /label= Protein_kinase_domain
FT   Domain          258. .349
FT                   /label= Protein_kinase_domain
FT   Domain          361. .390
FT                   /note= "Protein kinase C terminal domain"
XX
PN   WO200196547-A2.
XX
PD   20-DEC-2001.
XX
PF   14-JUN-2001; 2001WO-US019444.
XX
PR   15-JUN-2000; 2000US-0212073P.
PR   23-JUN-2000; 2000US-0213467P.
PR   30-JUN-2000; 2000US-0215651P.
PR   07-JUL-2000; 2000US-0216605P.
PR   13-JUL-2000; 2000US-0218372P.
PR   25-AUG-2000; 2000US-0228056P.
XX
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PA (INCY-) INCYTE GENOMICS INC.
XX
PI Yue H, Lal P, Bandman O, Borowsky ML, Au-Young J, Lu Y;
PI Gandhi AR, Tribouley CM, Walia NK, Yao MG, Lu DAM, Greenwald SR;
PI Ramkumar J, Griffin JA, Kearney L, Burford N, Nguyen DB, Tang YT;
PI Baughn MR, He A, Thornton M, Hafalia A, Patterson C, Gururajan R;
PI Lo TP, Khan F, Recipon SA, Azimzai Y, Policky JL, Ding L;
PI Grether M, Elliott VS, Thangavelu K, Batra S, Ison CH;
XX
DR WPI; 2002-090207/12.
DR N-PSDB; AAD26454.
XX
PT New polypeptides, useful for diagnosing, treating or preventing disorders
PT of growth and development, cardiovascular and lipid, and diseases such as
PT cancer, comprise human kinase polypeptides.
XX
PS Claim 1; Page 146-147; 197pp; English.
XX
CC The invention relates to human kinase PKIN proteins and their
CC corresponding cDNAs. A composition containing PKIN agonist is useful for
CC treating a disease or condition associated with decreased expression of
CC PKIN and a composition comprising PKIN antagonist is useful for treating
CC a disease or condition associated with overexpression of PKIN. The
CC disorders include cancer (leukaemia, adenocarcinoma, lymphoma, melanoma,
CC myeloma, sarcoma, teratocarcinoma, Hodgkin's disease); immune disorder
CC (Acquired Immune Deficiency Syndrome (AIDS), asthma, Addison's disease,
CC atherosclerosis, anaemia, allergies, adult respiratory distress syndrome,
CC autoimmune thyroiditis, gout, bronchitis, Crohn's disease, diabetes
CC mellitus, multiple sclerosis, Good pasture's syndrome, Graves' disease,
CC osteoarthritis, osteoporosis, pancreatitis, psoriasis, Reiter's syndrome,
CC rheumatoid arthritis, Sjogren's syndrome, uveitis, ulcerative colitis,
CC bacterial, parasitic, fungal, viral, protozoal and helminthic infections)
CC growth and development disorders (arteriosclerosis, cirrhosis, hepatitis,
CC Cushing's syndrome, hypothyroidism, cerebral palsy, cataracts); cardio
CC vascular disease (arteriovenous fistula, hypertension, vasculitis,
CC aneurysms, congestive heart failure, angina pectoris, myocarditis,
CC ischaemic heart disease, chronic bronchitis, lung tumours); lipid
CC disorder (fatty liver, Fabry's disease, Niemann-Pick's disease,
CC hypocholesterolaemia, obesity). PKIN DNA is useful for assessing toxicity
CC of a test compound and in gene therapy. The present sequence is human
CC PKIN-7 protein
XX
SQ Sequence 497 AA;

Query Match 98.0%; Score 1287; DB 5; Length 497;
Best Local Similarity 100.0%; Pred. No. 7.2e-127;
Matches 252; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

```
Qy          1 MLKFKYGARNPLDAGAAEPIASRASRLNLFFQGKPPFMTQQQMSPLSREGILDALFVLFE 60
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Qy         61 ECSQPALMKIKHVSNFVRKYSDTIAELQELQPSAKDFEVRSLVGCGHFAEVQVVREKATG 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy        121 DIYAMKVMKKKALLAQEQVSFFEEERNILSRSTSPWIPQLQYAFQDKNHLYLVMEYQPGG 180
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                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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                ||||||||||||
Db        241 GSAAKMNSNKMV 252
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```
RESULT 5
US-10-028-946-4
; Sequence 4, Application US/10028946
; Publication No. US20020123622A1
; GENERAL INFORMATION:
;  APPLICANT: Yu, Xuanchuan
;  APPLICANT:  Miranda, Maricar
;  APPLICANT:  Friddle, Carl Johan
;  TITLE OF INVENTION: No. US20020123622A1el Human Kinases and Polynucleotides Encoding the Same
;  FILE REFERENCE: LEX-0289-USA
;  CURRENT APPLICATION NUMBER: US/10/028,946
;  CURRENT FILING DATE:  2001-12-20
;  PRIOR APPLICATION NUMBER: US 60/258,335
;  PRIOR FILING DATE: 2000-12-27
;  NUMBER OF SEQ ID NOS: 4
;  SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 4
;   LENGTH: 1958
;   TYPE: PRT
;   ORGANISM: homo sapiens
US-10-028-946-4

  Query Match             98.0%;  Score 1287;  DB 4;  Length 1958;
  Best Local Similarity   100.0%;  Pred. No. 3.9e-101;
  Matches  252;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MLKFKYGARNPLDAGAAEPIASRASRLNLFFQGKPPFMTQQQMSPLSREGILDALFVLFE 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy         61 ECSQPALMKIKHVSNFVRKYSDTIAELQELQPSAKDFEVRSLVGCGHFAEVQVVREKATG 120
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Qy        121 DIYAMKVMKKKALLAQEQVSFFEEERNILSRSTSPWIPQLQYAFQDKNHLYLVMEYQPGG 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy        181 DLLSLLNRYEDQLDENLIQFYLAELILAVHSVHLMGYVHRDIKPENILVDRTGHIKLVDF 240
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Qy        241 GSAAKMNSNKMV 252
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Db        241 GSAAKMNSNKMV 252
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